GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:749
ANSWERED ON:22.10.2008
METAL CONTENTS IN MEDICINES
Rao Shri Sambasiva Rayapati

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the medicines containing excess metal contents than the prescribed limit are sold across the country;

(b) if so, the details thereof including its ill-effects;

(c) whether the Government has ordered any inquiry in this regard;

(d) if so, the outcome thereof; and

(e) the steps taken by the Government in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE(SMT. PANABAKA LAKSHMI)

(a) to (e): No, Sir. The Ayurveda, Siddha and Unani (ASU) medicines containing plants/ herbal, herbo-minerals and herbo-metallic preparations are being manufactured in India on valid licenses under the Drugs and Cosmetics Act 1940, and Rules 1945. The herbo-mineral and herbo- metallic preparations are permitted to be used only after due purification and only in small quantities to act as catalysts for activation of other herbal ingredients in order to increase the efficacy of the medicines. The metallic preparations in the form of compounds of metals triturated in the form of Bhasmas are rendered safe after purification with herbs and burning in fire for a prescribed number of times.

The following steps have been taken from time to time in order to ensure the safety and efficacy of ASU medicines:

(i) Mandatory testing for heavy metals has been introduced w.e.f. 01.01.2006 for herbal Ayurveda, Siddha and Unani medicines which are being exported. This has been done to meet the regulatory requirements of importing countries.

(ii) State Drug Licensing Authorities have been directed to ensure full compliance by all ASU drug manufacturers with the provisions of Rule 161 (1) and (2) relating to displaying, on the label of the container or in a leaflet to be inserted in the package of an ASU drugs, a list of all the ingredients along with quantities used in the manufacture of the preparation.

(iii) Under a Centrally Sponsored Scheme, 29 State Drug Testing Laboratories have been strengthened and 26 Private Drug Testing Laboratories and other NABL accredited laboratories have been approved for testing of ASU drugs in the country.

(iv) Captain Srinivasa Murti Drug Research Institute for Ayurveda, Chennai, India Toxicology Research Centre (presently IITR), Indian Institute of Toxicological Research), Lucknow and Sri Ram Institute for Industrial Research, New Delhi have analyzed about 600 plants and it was found that lead, arsenic and mercury levels were with the permissible limits.

(v) Good Manufacturing Practices have been made mandatory for all Ayurveda, Siddha and Unani drug manufacturing units in the country through an amendment of Schedule T of Drugs and Cosmetics Rules, 1945.

(vi) In order to create quality consciousness among both manufacturers and consumers, a National Campaign on Quality Assurance of AYUSH Drugs was launched on 10-11 June, 2008 through a National Workshop. The National Campaign is being taken forward countrywide through five Regional Workshops in the East, West, North, South and Central Regions.